IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CARDINAL HEALTH, INC. Plaintiff v. ERIC H. HOLDER JR., et al. Defendants.	No. 1:11-cv-_____.

MEMORANDUM OF POINTS AND AUTHORITIES
IN SUPPORT OF CARDINAL HEALTH'S
MOTION FOR TEMPORARY RESTRAINING ORDER

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INTRODUCTION

Cardinal Health, Inc. ("Cardinal Health"), one of the largest wholesale distributors of prescription drugs in the United States, respectfully requests a temporary restraining order ("TRO") to enjoin enforcement of an Immediate Suspension of Registration Order that the Drug Enforcement Administration ("DEA") issued yesterday and served today on the company's Lakeland, Florida distribution center. *See In the Matter of Cardinal Health*, Order to Show Cause & Immediate Suspension of Registration (Feb. 2, 2012) (Ex. A) ("ISO").[1] The ISO required the Lakeland facility to *immediately* halt shipment of *all* controlled substances—including important medications used to treat seizures, cancer patients, and children with attention deficit disorder—to approximately 5,200 customer accounts, including pharmacies and hospitals serving hundreds of thousands of patients. DEA does not allege that Cardinal Health has provided controlled substances to anyone not licensed by DEA to receive them. Rather, DEA has taken the extraordinary step of issuing the ISO because it contends that four of Cardinal Health's DEA-registered pharmacy customers have filled prescriptions for oxycodone that were for illegitimate uses. For the reasons explained below, all of the relevant factors for evaluating whether to issue a TRO favor relief here.

Likelihood of Success. Cardinal Health is likely to succeed on the merits of its challenge to the ISO. An ISO is DEA's most powerful enforcement sanction. It can be imposed without advance notice and without an opportunity for a hearing, and it has the potential to destroy businesses and livelihoods. ISOs are therefore reserved for addressing only the most dangerous activities of the most serious violators. The case law and the

[1] Exhibits referenced in this memorandum are attached to the declarations of Randolph D. Moss and Michael A. Moné, submitted herewith.

governing statute are clear: an ISO cannot be imposed unless DEA establishes that it is necessary to prevent an imminent danger to the public health or safety. 21 U.S.C. § 824(d). Here, DEA cannot meet that burden for at least four reasons:

First, immediate suspension of the Lakeland facility is unnecessary to address the problem DEA alleges—dispensing of controlled substances to illegitimate users by four pharmacies identified in the ISO—because Cardinal Health is not currently supplying controlled substances to those pharmacies. Cardinal Health already suspended distributions to the two named independent pharmacies months ago, and has temporarily suspended distributions to the two named CVS pharmacies while the court considers this motion. Additionally, Cardinal Health has pledged promptly to terminate sales of controlled substances to any pharmacy or other customer that DEA believes is likely engaged in illegal activity or diversion.

Second, Cardinal Health maintains a vigorous and robust anti-diversion system, which has been described by DEA's own inspectors and investigators as one of the best among wholesale distributors nationwide. Indeed, Cardinal Health's anti-diversion system, in important aspects, is more comprehensive than DEA's own enforcement efforts. Since January 1, 2009, Cardinal Health has ceased distribution of controlled substances to 315 pharmacies. Of these, 216 still have DEA registrations today. Of the more than 149 pharmacies in Florida to which Cardinal Health suspended controlled substance shipments during the same time period, 113 still retain DEA registrations today. In the last three months alone, Cardinal Health has suspended shipments of controlled substances to 30 DEA-registered pharmacies in Florida.

Third, it is undisputed that Cardinal Health has distributed controlled substances only

to DEA-registered pharmacies and health care facilities. DEA does not allege that the Lakeland facility has sold or distributed a single dose of oxycodone outside this closed system of authorized distribution. The sole basis for DEA's ISO against the Lakeland facility is the allegation that 4 of Cardinal Health's pharmacy customers have filled oxycodone prescriptions for allegedly illegitimate purposes. But any concerns about these pharmacies can be addressed by suspending their DEA registrations to distribute controlled substances. Suspension of Cardinal Health's distribution facility is not necessary to address harm caused by the actions of third parties subject to direct DEA regulation.

Fourth, the ISO will not halt or reduce diversion of controlled substances by anyone and therefore does not diminish the "imminent danger" that DEA alleges. The customers of the Lakeland facility that retain DEA registrations will continue to receive controlled substances from other distributors. In fact, because these distributors may not have the same robust anti-diversion controls as Cardinal Health does, the ISO likely will exacerbate the risk of diversion, if it has any effect at all.

Irreparable Harm. A TRO is also necessary to prevent irreparable harm to Cardinal Health and its customers. The Lakeland facility supplies thousands of hospitals, pharmacies, and other health care providers. The facility's customers require prompt delivery of controlled substances for thousands of oncology, surgery, urgent care, emergency room, and hospice care patients. In the absence of a TRO, DEA's actions will cause serious disruption in the supply chain for controlled substances, resulting in delays in treatment for legitimate patients already facing drug shortages. This, in turn, would cause severe and irreparable harm to Cardinal Health. The company would suffer significant damage to its business reputation and loss of customer goodwill. Some customers will

likely stop doing business with Cardinal Health and never return. Additionally, the ISO will cause Cardinal Health to lose significant revenue that it could never recover. Cardinal Health has no adequate remedy at law if this Court does not immediately enjoin DEA from enforcement of the ISO.

Balance of Hardships. The balance of hardships also supports issuing a TRO. As explained above, there is no imminent danger to the public health that requires an immediate suspension of Cardinal Health's registration. Also, in the same notice as the ISO, DEA served an Order to Show Cause, initiating a DEA administrative process for considering whether revocation of the Lakeland facility's registration is appropriate. *See* Ex. A. DEA could also pursue a judicial enforcement mechanism provided for in a 2008 agreement it entered into with Cardinal Health. In either case, DEA would be required to give advance notice to Cardinal Health and provide it an opportunity to respond to the allegations against it. But in the absence of an imminent danger to the public, there is no need—or legal basis—to deprive Cardinal Health of the process afforded by law.

Public Interest. Finally, the public interest weighs heavily in favor of granting a TRO. As noted above, the ISO is not necessary to prevent any imminent harm to the public. By delaying shipments, however, a TRO would cause injury to the numerous patients that depend on Cardinal Health for an uninterrupted supply of medications for their legitimate medical needs.

Accordingly, Cardinal Health respectfully requests that the Court temporarily enjoin enforcement of the ISO until the Court can rule on a motion for a preliminary injunction to be filed by Cardinal Health.

BACKGROUND

I. Regulatory Scheme

The Controlled Substances Act ("CSA") and its implementing regulations establish restrictions on the distribution of controlled substances. 21 U.S.C. § 801 *et seq.*; *id.* § 951 *et seq.*; 21 C.F.R. Part 1300 *et seq.* The distribution of controlled substances without a DEA registration is a felony offense. 21 U.S.C. § 841(a). DEA is charged with enforcing the CSA in a balanced manner that prevents the diversion of controlled substances from legitimate channels while ensuring their availability for legitimate medical purposes. *See* 76 Fed. Reg. 39, 318, 39,318 (July 6, 2011).

Under the CSA, DEA can revoke, restrict, or suspend a registration upon one of five findings, only one of which is even arguably relevant here—that the registrant has committed acts that render the registration inconsistent with the public interest. 21 U.S.C. § 824(a)(4). Prior to revoking or restricting a DEA registration, DEA must generally follow procedures designed to provide a registrant with notice and an opportunity to be heard. It must issue an order to show cause setting forth the basis for the agency's proposed action and providing the registrant with the opportunity to request a hearing. *See id.* § 824(c). At such a hearing, the government has the burden of proving by a preponderance of evidence that registration is inconsistent with the public interest. 21 C.F.R. § 1301.44(d).[2]

DEA may issue an ISO—without providing a registrant with prior notice or an

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[2] As noted above, *see supra* at 4, DEA issued an order to show cause for the Lakeland distribution center simultaneously with the ISO. Cardinal Health is not seeking to enjoin DEA from holding that hearing. Instead, Cardinal Health seeks to enjoin enforcement of the ISO, so that the Lakeland facility will be permitted to continue distributing controlled substances until it has an opportunity to be heard. By declining to seek injunctive relief to block the DEA hearing on the Order to Show Cause, Cardinal Health does not estop itself from seeking—or waive its right to seek—injunctive relief, or judicial review, following the administrative hearing. Of course, whether injunctive relief will be necessary after the administrative hearing cannot be determined now.

opportunity to respond to DEA's allegations—only if the continued registration poses an "imminent danger to the public health or safety." 21 U.S.C. § 824(d); 21 C.F.R. § 1301.36(e).

II. Cardinal Health And Its Lakeland Facility

Cardinal Health, a Fortune 500 company with its corporate headquarters in Dublin, Ohio, is one of the largest prescription drug wholesale distributors nationwide. Declaration of Jon Giacomin ("Giacomin Decl.") ¶ 5. It has distribution centers throughout the United States. *Id.* Before receiving the ISO, the Lakeland facility, which has held a DEA registration since 2003, shipped an average of about 4 million dosage units of prescription drugs, including about 500,000 dosage units of controlled substances, on a monthly basis to more than 5,200 customer accounts in Florida, Georgia, and South Carolina. *Id.* The volume of prescription drugs distributed makes the Lakeland facility the largest prescription drug wholesaler in Florida. *Id.* The percentage of controlled substances sold by the Lakeland facility (12%, *see id.*) is within the range that DEA considers normal (5% to 20%).[3]

III. The 2008 Memorandum Of Agreement With DEA

In 2007, DEA issued immediate suspension orders and orders to show cause directed at certain distribution centers of the three largest wholesale distributors (including Cardinal Health) alleging, among other things, that the companies had failed to maintain effective controls against diversion by Internet pharmacies. Declaration of Michael A.

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[3] *See id.*; Southwood Pharmaceuticals, Inc., 72 Fed. Reg. 36,487, 36,492 (DEA July 3, 2007) ("[I]n a typical retail pharmacy, controlled substances might amount to between five and twenty percent of the pharmacy's purchases" (testimony of Michael Mapes, then Chief of the DEA Office of Diversion Control's E-Commerce Section) (internal quotation marks omitted)).

Moné ("Moné Decl.") ¶ 27. In September 2008, Cardinal Health and DEA reached a settlement of those matters, which was memorialized in a Memorandum of Agreement. *See* Settlement & Release Agreement & Administrative Memorandum of Agreement (Sept. 30, 2008) (Ex. M1) ("MOA"). The MOA required Cardinal Health "to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations." MOA at 3. The MOA also provides that "either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party." MOA at 9.

IV. Cardinal Health's Commitment To Detecting And Preventing Diversion

Cardinal Health has established and implemented a comprehensive compliance program—the Suspicious Order Monitoring ("SOM") program. Moné Decl. ¶¶ 9-25. A total of 16 employees are dedicated full-time to controlled substance compliance, and another 25 compliance officers are based in the field. *Id.* ¶ 9. Under the program, Cardinal Health first gathers information about its potential customers under its "Know Your Customer" procedure. *Id.* ¶¶ 11-14; Ex. M2 (questionnaire potential customers must complete). It then establishes, on a customer-specific basis, appropriate ordering thresholds for classes of controlled substances and evaluates whether to adjust a given customer's thresholds based on changed circumstances. Moné Decl.. ¶¶ 15-18. If a customer's order would exceed the established threshold, Cardinal Health conducts an investigation to determine whether diversion of the order appears likely if it is filled. *Id.* ¶¶ 19-21. These investigations can include a site visit by seasoned Cardinal Health investigators with law enforcement or regulatory investigation experience. *Id.* ¶¶ 12, 21. DEA reviewed Cardinal Health's SOM program and was provided further information about the program on multiple occasions. *Id.* ¶¶ 28-29, 35-36. DEA's own inspectors have described Cardinal Health's

SOM program as one of the best among wholesale drug distributors nationwide. *Id.* ¶ 29.

Since January 1, 2007, Cardinal Health has suspended shipment of controlled substances to more than 375 customers, including more than 180 pharmacies in Florida, that it believed posed an unreasonable risk of diversion. *Id.* ¶ 23. In the last three months alone, Cardinal Health has suspended shipments of controlled substances to 30 DEA-registered pharmacies in Florida. *Id.* ¶ 43. In 2011, Cardinal Health also rejected, at the initial review stage, applications of 55 pharmacies seeking to obtain controlled substances. *Id.* ¶ 11. In many respects, Cardinal Health's compliance program is more stringent than DEA's: a large percentage of pharmacies suspended by Cardinal Health still retain their DEA registration. Since January 1, 2009, of the 315 pharmacies suspended by Cardinal Health nationwide, 216 maintain an active DEA registration today, even though Cardinal Health notified DEA about each termination. *Id.* ¶ 23. During the same time period, Cardinal Health suspended controlled substance shipments to more than 149 pharmacies in Florida, but 113 still have registrations today. *Id.* Indeed, a federal court in Oklahoma once questioned Cardinal Health's decision to terminate a pharmacy, in part because there had been no "adverse regulatory action against it." *Apothecaryx, LLC v. Cardinal Health 110, Inc.*, No. 5:07-cv-01399-D (W.D. Okla. Dec. 17, 2007) (temporary restraining order).

Cardinal Health continues to strive to improve its systems. For instance, it recently began coordinating its anti-diversion efforts with oxycodone manufacturer Mallinckrodt, Inc. *Id.* ¶¶ 39-40. In fall 2011, Mallinckrodt shared information (previously unknown to Cardinal Health) about purchases of controlled substances by specific Florida pharmacies through multiple wholesalers. *Id.* That information prompted Cardinal Health to suspend sales of controlled substances to certain customers that presented an unreasonable risk of

diversion. *Id.* ¶ 40. Cardinal Health intends to continue cooperation with Mallinckrodt. *Id.*

DEA has even better data than Mallinckrodt because *all* distributors are required to regularly report to DEA their total distributions to pharmacies of Schedule II drugs and narcotic Schedule III drugs through DEA's "ARCOS" system.[4] DEA itself recognizes the value of data unavailable to a single distributor. It has told distributors that one indication of diversion by a pharmacy is whether it is "[o]rdering the same controlled substances from multiple distributors." Letter from Deputy Assistant Administrator Joseph T. Rannazzisi to Cardinal Health at 3 (Feb. 7, 2007) (Ex. B). Yet DEA has declined to provide information about pharmacies' purchases in response to frequent requests by Cardinal Health and the wholesale industry. Moné Decl. ¶¶ 37-38.[5] In addition, just over three months ago, Cardinal Health requested that DEA inform it "of the identity of any Cardinal Health customer that the agency has determined is engaged in the diversion of controlled substances." Letter from Craig Morford, Chief Legal and Compliance Officer, to Adm'r Michele M. Leonhart (Oct. 27, 2011) (Ex. C). In that letter, Cardinal Health made clear to DEA that it would "immediately cease distribution of controlled substances to any customer that DEA so identifies." *Id.* Cardinal Health subsequently reiterated its request for information about any of its "customers that the DEA believes are likely engaged in illegal activity or diversion." E-mail from Jamie Gorelick to Chief Counsel Wendy H. Goggin (Dec. 22, 2011) (Ex. D). DEA rejected Cardinal Health's requests. Moné Decl. ¶ 38.

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[4] 21 U.S.C. § 827(d); 21 C.F.R. § 1304.33.

[5] The Healthcare Distribution Management Association ("HDMA"), which represents the interests of wholesale distributors like Cardinal Health, requested this data, called "ARCOS" data, in meetings with DEA in February 2009 and December 2010, and in letters in July 2010 and June 2011. *See* Moné Decl. ¶ 37; Letter from John M. Gray, President of Healthcare Distribution Management Ass'n, to Administrator Michele M. Leonhart, p. 10 (June 1, 2011). (Ex. E); HDMA, Summary of the DEA-HDMA Meeting Held on Dec. 7, 2010, p. 2 (Ex. F).

Even without DEA's assistance, Cardinal Health continues to combat potential oxycodone diversion by its customers. Because of reports of oxycodone abuse in Florida, in November 2010 Cardinal Health sent teams of compliance investigators and pharmacists to gather data on and perform inspections of 53 of its largest retail independent pharmacy customers in Florida. *Id.* ¶ 33. This investigation resulted in suspension of shipments of controlled substances to several of the 77 Florida pharmacies to which Cardinal Health had temporarily halted such sales in the last three years. *Id.*

V. The February 2, 2012 Immediate Suspension Order

Despite Cardinal Health's extensive compliance program, on February 2, 2012, DEA issued the ISO. DEA then served the ISO on February 3, 2012, immediately suspending the Lakeland facility's controlled substances registration. Ex. A. In the same notice as the ISO, the DEA also served an Order to Show Cause initiating DEA administrative procedures to revoke the Lakeland facility's controlled substances registration. *Id.*

The ISO alleges that continued registration of the Lakeland facility presents an imminent danger to the public health or safety because, according to the ISO, Cardinal Health's compliance program is ineffective. *See id.* at 2-3. The sole basis for this assertion is DEA's contention, that 4 pharmacy customers of Cardinal Health have distributed oxycodone for illegitimate uses. *See id.* at 2. The ISO does not allege that Cardinal Health itself has distributed controlled substances to any entity not permitted to purchase them. Rather, it alleges that Cardinal Health should have known that 4 of its pharmacy customers were filling prescriptions for allegedly illegitimate purposes. *Id.* at 3.

Cardinal Health already suspended distributions to the two named independent pharmacies months ago (one on September 26, 2011 and the other on October 5, 2011), and has temporarily suspended distributions to the two named CVS pharmacies while the court

considers this motion. *Id.* ¶¶ 48, 55.

VI. The ISO's Effects on Cardinal Health

If the ISO is not enjoined, Cardinal Health would be forced to reroute controlled substances previously distributed from its Lakeland distribution center to its distribution centers in Greensboro, North Carolina; Madison, Mississippi; and Denver, Colorado. Giacomin Decl. ¶¶ 7-9. This rerouting would cause delays in the receipt of controlled substances by Cardinal Health's Florida customers. *Id.* ¶¶ 8-9. Those customers, who typically receive next day shipments from the Lakeland facility, would have to wait up to three days for shipments from the Denver facility and two days for shipments from other facilities. *Id.*¶¶ 6, 8-9.

The ISO's effects would be severe. The Lakeland facility's primary customers include hospitals, nursing homes, retail independent pharmacies, and urgent care centers that place orders on a daily basis. *Id.* ¶ 5. Because there is currently a shortage of certain controlled substances in the United States, those customers will not always be able to secure needed medications from secondary vendors. *Id.* ¶¶ 15-16. Indeed, even before the ISO was issued, it was difficult for critically ill patients to obtain the pain medication they needed. *See* David S. Craig, *Cancer Patients Denied Needed Pain Treatment*, St. Petersburg Times, Dec. 8, 2011, at 11A (Ex. G) ("As Florida officials have cracked down on 'pill mills'—medical clinics that illegally and unethically distribute pain medications while masquerading as legitimate pain management clinics—the effort has hindered the legitimate use of these medications. As a result, cancer patients are finding it harder to get the pain medications they need."). For Cardinal Health's customers, disruptions in supply can equate to disruption in patient care and delays in treatment for seriously ill or terminal patients. Giacomin Decl. ¶ 10.

As a result of the delays, some Lakeland facility customers will likely leave Cardinal Health permanently for other distributors—as occurred in the wake of the 2007 ISO. *Id.* ¶ 20-22. Most customers prefer to order pharmaceuticals from a single large distributor because it is not cost effective to order controlled substances and non-controlled substances from different distributors. *Id.* ¶ 20. Some portion of the Lakeland facility's customers thus is expected to take their entire pharmaceutical business to Cardinal Health's competitors. *Id.*; *see also id.* ¶¶ 21-22.

ARGUMENT

Cardinal Health is entitled to a TRO enjoining DEA's ISO pending further proceedings in this case. The purpose of a TRO is to protect against irreparable injury and to preserve the status quo until the Court can render a meaningful decision on the merits. *Barrow v. Graham,* 124 F. Supp. 2d 714, 715-16 (D.D.C. 2000). Under the traditional test for issuing a TRO or a preliminary injunction, the court must consider whether "(1) the plaintiff has a substantial likelihood of success on the merits; (2) the plaintiff would suffer irreparable injury were an injunction not granted; (3) an injunction would substantially injure other interested parties; and (4) the grant of an injunction would further the public interest." *Sottera, Inc. v. FDA,* 627 F.3d 891, 893 (D.C. Cir. 2010).

As explained below, all four factors compel the issuance of a TRO in this case. Most critically, DEA cannot establish an imminent danger to the public health or safety from continued registration of the Lakeland facility. This alone is a sufficient basis for issuing the TRO. *See Norman Bridge Drug Company v. Banner*, 529 F.2d 822, 828 (5th Cir. 1976) ("[i]n the absence of that indispensable element, imminent danger to the public health and safety, all else was beside the point").

I. Cardinal Health Is Likely To Succeed On The Merits

Cardinal Health is likely to succeed on the merits because DEA has not met the strict standard for suspending a registrant without notice and an opportunity to be heard, its decision is otherwise arbitrary and capricious, and DEA has deprived Cardinal Health of due process.

A. DEA Has Failed To Establish Imminent Danger To Public Health Or Safety

Cardinal Health's challenge to the ISO is likely to succeed because DEA cannot establish that suspension of the Lakeland facility's registration is necessary to prevent an imminent danger to the public health or safety. Orders by DEA affecting a company's registration are subject to review under the standards set forth in the APA. *Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005) (vacating DEA decision to revoke physician's DEA registration); *Wedgewood Village Pharmacy v. DEA*, 509 F.3d 541, 549 (D.C. Cir. 2007) (vacating DEA decision to revoke pharmacy's DEA registration). Review of an order for immediate suspension under § 824(d) may be sought in district court without awaiting further action by DEA. *See Novelty Distribs., Inc. v. Leonhart*, 562 F. Supp. 2d 20, 24-28 (D.D.C. 2008); *Norman Bridge*, 529 F.2d at 828-29; *Neil Laboratories, Inc. v. Ashcroft*, 217 F. Supp. 2d 80, 84 n.6 (D.D.C. 2002); *see also* 21 U.S.C. § 824(d) (providing that an ISO can be "dissolved by a court of competent jurisdiction").

As noted above, an ISO may be issued only when necessary to protect the public health or safety from an "imminent danger." 21 U.S.C. § 824(d); *see Norman Bridge*, 529 F.2d at 828; *PRSI Acquisition Group, LLC v. Ashcroft,* No. 02-cv-1020, slip op. at 2 (D.D.C. May 30, 2002) (order granting preliminary injunction) ("DEA's finding of imminent danger was arbitrary and capricious") (Ex. H); *Bates Drug Stores,*

Inc. v. Holder, No. CV–11–0167–EFS, 2011 WL 1750066, at *4 (E.D. Wash. May 6, 2011) (enjoining Immediate Suspension Order under 21 U.S.C. § 824(d)). This heightened standard is necessary to ensure that registrants are not deprived of their registrations without due process of law. As explained below in § I(C), revoking a registration without notice and an opportunity to be heard can be justified—if ever—only in extraordinary circumstances. In order to avoid raising constitutional concerns, § 824(d)'s "imminent danger" standard should be interpreted to require that DEA carry the heavy burden of showing that immediate suspension is necessary to prevent a concrete and imminent threat to public safety that cannot be avoided through less drastic measures. *See Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. & Const. Trades Council*, 485 U.S. 568, 575 (1988). Here, continued registration of the Lakeland facility presents no imminent danger to the public health for multiple reasons.

1. Cardinal Health Has Already Suspended Sales To The Pharmacies Identified In The ISO And Stands Ready To Terminate Sales To Any Other Pharmacy DEA Believes Poses A Risk Of Diversion

Immediate suspension of Cardinal Health's registration is not necessary to prevent the harm that DEA has identified—dispensing of controlled substances for illegitimate uses by four pharmacies identified in the ISO. Cardinal Health already suspended distributions to the two named independent pharmacies months ago, and has temporarily suspended distributions to the two named CVS pharmacies while the court considers this motion. *See* Moné Decl. ¶¶ 48-49, 55-56. The suspension of these pharmacies eliminates any arguable danger to the public health. Indeed, similar corrective action caused this Court to preliminarily enjoin an ISO in *PRSI Acquisition*. In that case, the Court found that any imminent danger had been resolved because the employee whose conduct gave rise to

the ISO had been terminated. *PRSI Acquisition*, No. 02-cv-1020, at 2 (Ex. H).

Moreover, Cardinal Health stands ready and willing to cease distributions to any customer that poses an undue risk of diversion. As noted above, *see supra* at 2; Ex. D, Cardinal Health has made clear to DEA that it will suspend controlled substance shipments to any pharmacy the agency identifies as posing an undue risk of diversion. Such a suspension would eliminate any risk of harm to public health asserted by DEA in the ISO.

2. Cardinal Health Has An Effective Anti-Diversion Program

Cardinal Health's continued registration also poses no imminent danger to the public health because the company maintains a robust anti-diversion system, described by DEA's own inspectors as one of the best among wholesale drug distributors nationwide, *see* Moné Decl. ¶ 29. As noted above, over 40 Cardinal Health employees are dedicated to compliance. *See supra* at 7.[6] Cardinal Health establishes and reviews ordering thresholds for its customers, monitors its customers' purchases of controlled substances, and investigates potentially suspicious orders. *See id.* As explained above, DEA has reviewed Cardinal Health's SOM system and has been provided with information about updates to the system since 2009 yet has never previously raised any significant concerns about the system. *See* Moné Decl. ¶¶ 28-29, 35-36.

The DEA now contends in the ISO that Cardinal Health's SOM program is ineffective. But the ISO provides no basis for this conclusion. DEA cannot dispute the fact that Cardinal Health already suspended distribution to the two named independent

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[6] Cardinal Health's commitment to combating diversion is evident from the leadership team it assembled to run its SOM program. In May 2008, Cardinal Health hired former acting Deputy Attorney General Craig Morford to serve as Chief Legal and Compliance Officer. Moné Decl. ¶ 3. In December 2007, Cardinal Health hired Michael Moné as Vice President for Supply Chain Integrity. *See id.* Mr. Moné, both a lawyer and a pharmacist, has extensive experience with pharmacy regulation and anti-diversion efforts. *See id.* ¶ 2.

pharmacies months ago, and has temporarily suspended distributions to the two named CVS pharmacies while the court considers this motion. DEA relies primarily on the volume of controlled substances ordered by the pharmacies. But the agency itself recently held that the volume of controlled substances alone, even in an area notorious for oxycodone abuse, was inconclusive evidence of diversion. *Carlos Gonzalez, M.D.*, 76 Fed. Reg. 63,118, 63,138 (DEA Oct. 11, 2011). High volumes of controlled substance sales to a pharmacy might mean only that the pharmacy serves a higher than average volume of legitimate acute pain patients (for example, if a pharmacy is located near an oncology clinic or a hospice, or has a higher than average proportion of elderly customers). *Cf. id.* ("[T]here are a host of factors that could account for … the Respondent's level of controlled substance prescribing ….").

To determine whether high sales volumes are suspicious, a distributor must consider other information. DEA consider a multitude of factors relating to public health needs in determining the appropriate quotas for the amount of controlled substances that can be manufactured in the United States.[7] Cardinal Health and other distributors—which like DEA must also fulfill public health obligations—are justified in considering similar factors in setting thresholds for their purchasers. While DEA criticizes the effectiveness of Cardinal Health's SOM program in detecting diversion, the difficulty of determining whether a facially valid prescription is being filled for illegitimate purposes has also been recognized by DEA. As Joseph Rannazzisi, DEA's Deputy Assistant Administrator in charge of the Office of Diversion Control, has publicly stated, "[a] tremendous challenge for

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[7] *See National Drug Threat Assessment, 2010,* U.S. Department of Justice, National Drug Intelligence Center, Feb. 2010, available at http://www.justice.gov/ndic/pubs38/38661/rx.htm (factors supporting quota increases include "more aggressive pain treatment, new and different indications for legitimate medical use, the increase in the average age of the citizenry, new delivery methods and formulations for opioid pain relievers, new product development, and exportation").

law enforcement when dealing with pharmaceutical controlled substances is often distinguishing among legitimate medical uses and illegal uses."[8] DEA, as a law enforcement and regulatory agency, has far more potent and comprehensive investigative tools than does a wholesale distributor like Cardinal Health. As difficult as it is for DEA to distinguish between legitimate and illegal uses, it is a much more challenging task for wholesalers that distribute to DEA-registered pharmacies to determine whether prescriptions written by DEA-registered doctors are actually being diverted to illegitimate uses.

Here, Cardinal Health monitored and investigated orders placed by both the 2 retail independent pharmacies and the 2 CVS pharmacies named in the ISO and formed reasonable conclusions that continued sales to them were appropriate based on the information available at the time. Moné Decl. ¶¶ 50-53, 57.

a. The Retail Independent Pharmacies

Cardinal Health's distribution of controlled substances to the 2 retail independent pharmacies named in the ISO is no basis for an immediate suspension under § 824(d). Cardinal Health makes decisions to distribute controlled substances to a retail independent pharmacy based on myriad factors. It considers (among other things) a pharmacy's size, history of dispensing, and location (including whether hospitals, pain clinics, orthopedic clinics, or hospices are nearby). *Id.* ¶ 16, 20. The information available to Cardinal Health about a pharmacy's dispensing practices, however, is limited. Unlike DEA and pharmacists, Cardinal Health investigators cannot obtain individual patients' prescriptions to determine whether they were issued for a legitimate medical purpose. *Id.* ¶ 26.

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[8] *DEA: Working to Halt the Diversion and Abuse of Prescription Drugs* at 2, ONDCP Update Volume 2, Issue 2, Feb. 2011; available at http://www.whitehouse.gov/sites/default/files/ondcp/newsletters/ondcp_update_february_2011.pdf.

In this case, Cardinal Health sent an investigator to every retail independent pharmacy named in the ISO (repeatedly, for some pharmacies) long before learning of DEA's specific concerns. *Id.* ¶¶ 51-53. Based on the results of those investigations and the information available to it, Cardinal Health investigators concluded that continued shipment to those pharmacies was reasonable. *Id.* Detailed descriptions of Cardinal Health's consideration of each of the retail independent pharmacies named in the ISO are set forth in the Declaration of Michael Moné. *See* Moné Decl. ¶¶ 43-44. As explained in that declaration, Cardinal Health considered precisely the kinds of factors that DEA endorsed in *Gonzalez* and elsewhere to detect diversion: the specialties and credentials of prescribing practitioners; volumes of certain controlled substances believed to be indicative of likely diversion; percentage of cash transactions for those medications; proximity of medical establishments with high volumes of patients with legitimate need for controlled substances; percentages of controlled substances to overall prescription drugs ordered by the pharmacy; and others. Accordingly, Cardinal Health's past distributions of controlled substances to these pharmacies is no basis for concluding that Cardinal Health's controls are ineffective, especially where those controls have led to the suspension of almost 150 pharmacies since January 2009.

b. The CVS Pharmacies

Cardinal Health's distribution to 2 CVS pharmacies similarly provides no basis for the ISO. Any diversion of oxycodone by these pharmacies cannot be attributed to a lack of diligence by Cardinal Health. The company's anti-diversion personnel work in cooperation with CVS, a large chain of retail pharmacies (about 7,000 nationwide) that sell prescription drugs, over-the-counter drugs, and other retail goods. Moné Decl. ¶ 10. As it does with independent pharmacies, Cardinal Health sets order thresholds for CVS and reviews orders

for controlled substances that exceed the thresholds. *Id.* ¶ 58. Cardinal Health held and investigated 1,690 orders from CVS pharmacies in the first ten months of 2011. *Id.* ¶ 59.

When Cardinal Health identified potentially unusual oxycodone-ordering patterns in the fall of 2010 at the CVS pharmacies identified in the ISO (and others), it requested that CVS investigate those orders. *Id.* ¶ 60. CVS compliance personnel conducted what appeared to be adequate investigations at the relevant pharmacies, and the findings from those investigations were reported to Cardinal Health. *Id.* With respect to the two Sanford stores identified in the ISO, which Cardinal Health identified to CVS first, CVS reported that it had investigated the matter and that the orders of oxycodone were appropriate for the activity at those stores. *Id.* Subsequently, CVS sent Cardinal Health a letter outlining its investigation of additional Florida CVS stores that Cardinal Health had identified. *Id.*; Letter from Brian E. Whalen to Paul Farley (Jan. 6, 2011) (Ex. M4). The letter indicated that teams of CVS Pharmacy Supervisors and Regional Loss Prevention Managers visited the stores, interviewed pharmacy staff, and reviewed controlled substance ordering, receiving and dispensing procedures, controlled substance records and reports, and security. Ex. M4. The teams reportedly "found no evidence of controlled substance diversion or significant losses." *Id.* The letter noted that CVS was "confident that pharmacists and their staffs at these pharmacies understand how to minimize the risk of dispensing controlled substances, particularly opioids for pain management, for non-legitimate purposes." *Id.* Finally, it assured Cardinal Health that CVS was "comfortable with Cardinal continuing to ship controlled substances to these pharmacies." Based on these reports, Cardinal Health reasonably concluded that continued distributions to these stores were appropriate. Moné Decl. ¶ 57.

Cardinal Health had good reason to believe that the CVS anti-diversion program was reliable. Large chains like CVS have the resources to investigate potential diversion, and chain pharmacists do not share directly in any profits from diversion. *Id.* ¶¶ 10, 61. The head of Cardinal Health's compliance department, Michael Moné, had contacts with CVS pharmacy officials at numerous levels whom he reasonably believed to be diligent professionals of high integrity and good judgment. *Id.* ¶ 61. The response to Cardinal Health's inquiries about the Florida stores in 2010 appeared credible. *Id.* ¶ 60; Ex. M4. Indeed, Cardinal Health had previously informed DEA in 2009 that it relied on CVS compliance personnel to conduct these investigations, and DEA never expressed any objection. Moné Decl. ¶ 29. In these circumstances, an immediate suspension simply cannot be justified. *See Norman Bridge*, 529 F.2d at 829 (DEA's failure to act on violation for 7 months means violation does not pose an imminent danger to public health and safety). Focusing almost entirely on volume alone, DEA alleges in the ISO that the Lakeland facility should not have shipped 5 million doses of oxycodone in a 48-month period to a CVS pharmacy located in Sanford, Florida. *See* Ex. A at 2. The agency claims that the amount shipped was higher than the national average. *Id.* But the volume of oxycodone distributed by Cardinal Health to this CVS pharmacy appeared reasonable in light of information available to Cardinal Health about the pharmacy's size, location, and operating hours. Moné Decl. ¶ 54. The pharmacy is open seven days a week and is much larger than most retail independent pharmacies. *Id.* The amount of oxycodone Cardinal Health distributed to this CVS store was sufficient to fill only about 33 prescriptions per day, as estimated by Mr. Moné. *Id.* Because of the large volume of prescriptions typically filled at large CVS stores, Mr. Moné reasonably believed that the relatively small volume of oxycodone prescriptions

filled on a daily basis did not place this store in the same category as the "pill mills" that DEA has publicly warned distributors about. *Id.*

* * *

DEA has thus failed to show that Cardinal Health's SOM program is ineffective, either with respect to retail independent pharmacies or CVS pharmacies. To the extent, however, that DEA identifies any specific flaws in its SOM program, Cardinal Health stands willing and able to remedy the situation immediately.

3. DEA Has Not Alleged That Cardinal Health Distributed Controlled Substances Outside The Closed System Of Distribution

Suspension of Cardinal Health's Lakeland facility is not necessary to address the danger DEA alleges—that certain pharmacies have been improperly filling illegitimate oxycodone prescriptions. The CSA established "a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of" controlled substances. *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006). Here, DEA has not alleged Cardinal Health or its employees illicitly sold or otherwise distributed controlled substances outside the closed system of distribution. In fact, Cardinal Health distributes controlled substances only to customers with active, valid DEA registrations. Moné Decl. ¶ 4. DEA granted registrations to those customers because the agency determined that it was in the public interest to do so.[9] Yet, DEA now seeks to take the extraordinary step of suspending Cardinal Health's registration, despite the fact that every pharmacy to which Cardinal Health sold controlled substances was expressly authorized by DEA to purchase and resell those drugs.

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[9] The Attorney General, through DEA, may deny an application for registration if he determines that the issuance of such registration "would be inconsistent with the public interest." 21 U.S.C. § 823(f).

4. Suspending Lakeland Will Not Prevent Diversion By Third Parties

Suspension of Cardinal Health's Lakeland facility will not address the harm DEA alleges because it will not prevent pharmacies filling illegitimate prescriptions from simply obtaining controlled substances from another distributor. The "imminent danger" to public health or safety alleged by DEA is distribution of controlled substances to pharmacies that fill prescriptions that were not issued for a legitimate medical purpose. If this Court allows the ISO to stand, however, there is no evidence that the practitioners who prescribe, and the pharmacies that dispense, the controlled substances that concern DEA would alter their practices at all. Absent further action from DEA or from the pharmacies filling the prescriptions that these practitioners write (circumstances entirely outside of Cardinal Health's control), the same practitioners would doubtless continue to prescribe the same controlled substances to the same patients. Many of the pharmacies with DEA registrations would merely turn to other distribution sources to obtain controlled substances, suppliers that do not have anti-diversion programs as robust as Cardinal Health's, *see* Moné Decl. ¶ 35 (DEA official characterized Cardinal Health's monitoring program as "going above and beyond"). As a result, DEA cannot show that issuance of the ISO would prevent an imminent danger to public health and safety, a finding mandated by the CSA for the issuance of an ISO.

Indeed, an ISO is particularly inappropriate since DEA has known about the Lakeland facility's sales of oxycodone to these pharmacies—and to all other customers—for many months. One of Cardinal Health's obligations under the MOA is to provide DEA, on a monthly basis, a report of all sales transactions of controlled substances. *See* Moné Decl. ¶ 27; MOA art. II(1)(b) (Ex. M1). If DEA believed Cardinal Health's sales to DEA-registered pharmacies was creating an imminent danger to the public, it should have acted at

the time it learned of those sales, not months later. DEA's delay in imposing the ISO alone is reason enough to grant the TRO.

B. Issuance Of The ISO Was Arbitrary And Capricious, In Violation Of The APA

In addition to failing to meet the "imminent danger" standard of § 824(d), the ISO is arbitrary and capricious. Under the APA, agency action must be set aside if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with applicable law. *See* 5 U.S.C. § 706; *Morall*, 412 F.3d at 177. Here, DEA's ISO is arbitrary and capricious because DEA failed to consider alternative actions more reasonably tailored to addressing its diversion concerns as well as the impact that its ISO would have on the public health. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983); *International Ladies Garment Workers' Union v. Donovan*, 722 F.2d 795, 817 (1983) ("[I]t is absolutely clear from decisions by the Supreme Court and this court that such an artificial narrowing of options is antithetical to reasoned decisionmaking[.]").

First, DEA failed to consider other, more tailored means of addressing the oxycodone abuse problem in Florida, including, providing information to Cardinal Health and other distributors that will help them to identify diverters of controlled substances. Even more directly, instead of revoking a distributor's registration, DEA could address diversion, without affecting the distribution of controlled substances to legitimate patients, by suspending or revoking DEA registrations of practitioners writing oxycodone prescriptions for illicit purposes and of pharmacies that fill those prescriptions. A pharmacist is required by law to investigate whether each prescription it fills is issued for a legitimate medical purpose, an investigation that Cardinal Health, as a wholesaler, cannot conduct.[10] 21 C.F.R.

[10] As a distributor, Cardinal Health has limited information available to detect diversion.

§ 1306.04(a) (2011); *see* also Pharmacist's Manual, DEA Office of Diversion Control, Section IX, available at http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_content.htm #9 ("To dispense controlled substances, a pharmacist must know the requirements for a valid prescription which are described in this section," including that the prescription "must be issued for a legitimate medical purpose").

Second, despite the fact that DEA has stated that its role is to further the CSA's purpose to "prevent, detect, and eliminate the diversion of controlled substances . . . into the illicit market while ensuring a sufficient supply of controlled substances . . . for legitimate medical . . . purposes," 76 Fed. Reg. at 39,318 (July 6, 2011), DEA has failed to consider the drastic—and unnecessary—consequences that the ISO will have on legitimate patients and health care institutions. The ISO precludes shipment of *all* controlled substances, not just oxycodone. But there is nothing in the record establishing any potential harm to the public health as the result of sales of drugs other than oxycodone. Moreover, the ISO will cause the Lakeland facility's Florida hospital customers to experience delays of *at least* twenty four hours in receipt of their controlled substances. Giacomin Decl. ¶¶ 8-9. Hospitals generally do not keep a large inventory of even critical medicines on hand; rather, they depend upon prompt delivery from wholesalers. *See id.* ¶ 11. Prior to DEA's ISO, these shipments could have been made in as little as 3-6 hours in emergency situations. *Id.* ¶ 6. Many of these medications are in short supply and thus many of Cardinal Health's customers cannot look initially to secondary vendors. *Id.* ¶¶ 15-16. Accordingly, the ISO

For example, pursuant to the limitations of state law and the federal Health Insurance Portability and Accountability Act ("HIPAA"), Cardinal Health may not obtain patient-identifiable information from pharmacies or physicians. 42 U.S.C. § 1320d. This information is, however, available to pharmacists, physicians, and DEA as a regulatory and law enforcement agency.

would result in patients served by the Lakeland facility's Florida customers experiencing delays in treatment. *Id.* ¶¶ 10-13, 14-15, 19.

Finally, DEA has failed to consider the implications of rendering ineffective Cardinal Health's anti-diversion efforts in Florida. DEA investigators have regarded Cardinal Health's anti-diversion program as one of the best among wholesale drug distributors nationwide. Moné Decl. ¶ 29. Because pharmacies with DEA registrations might have to obtain controlled substances from smaller, regional wholesalers with less developed anti-diversion capabilities, the risk of diversion is even greater in Florida because of the ISO. DEA's failure to consider these consequences in issuing its ISO renders its decision arbitrary and capricious.

C. The ISO Violated Cardinal Health's Due Process Rights

DEA's issuance of an immediate suspension—without prior notice or an opportunity for Cardinal Health to be heard—also violated Cardinal Health's Fifth Amendment Right to Due Process. For Cardinal Health to succeed in a due process claim, the company must demonstrate that "(1) it has a protected interest, (2) the government deprived it of this interest, and (3) the deprivation occurred without proper procedural protections." *PDK Labs Inc. v. Reno*, 134 F. Supp. 2d 24, 32 (D.D.C. 2001) (Fifth Amendment protects plaintiff's liberty interests, which include ability to import and manufacture pseudoephedrine, a "listed chemical" regulated by DEA). Cardinal Health easily meets these three criteria.

Cardinal Health has a valid property interest in its DEA registration to receive and distribute controlled substances. *See Harline v. DEA*, 148 F.3d. 1199, 1204 (10th Cir. 1998) (physician's property interest in his DEA registration entitles him to a hearing before his registration could be suspended or revoked for alleged improper dispensing of controlled substances); *Novelty Distributors,* 562 F. Supp. 2d at 30 (noting "the property

interests of distributors" in their registrations). Deprivation of a protected interest without an opportunity for a hearing violates due process except in "rare and extraordinary situations." *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 570 n.7 (1972).

This case does not present an "extraordinary situation[] where some valid governmental interest is at stake that justifies postponing the hearing until after the event," *Boddie v. Connecticut*, 401 U.S. 371, 379 (1971); *Nat'l Council of Resistance of Iran v. Dep't of State*, 251 F.3d 192, 208 (D.C. Cir. 2001) (government must "make a showing of particularized need" in order to dispense with pre-deprivation process). As demonstrated above, DEA has failed to establish that Cardinal Health's continued registration poses an imminent danger to the public health or safety; indeed, if anything, suspension of that registration will harm the public health. Absent an imminent danger to the public health, there is no basis for depriving Cardinal Health of the procedural safeguards necessary to ensure that it is not erroneously deprived of its registration. *See Mathews v. Eldridge*, 424 U.S. 319, 335 (1976); *United States v. James Daniel Good Real Property*, 510 U.S. 43, 62 (1993) ("To establish exigent circumstances, the Government must show that less restrictive measures . . . would not suffice to protect the Government's interests"). The ISO thus constitutes a deprivation of Cardinal Health's property and liberty interests without due process of law.

* * *

For all of these reasons, Cardinal Health is likely to succeed on the merits of its challenges. DEA's ISO is unnecessary to prevent harm to the public, is arbitrary and capricious, and violates due process.

II. Cardinal Health And Its Customers Will Suffer Irreparable Harm Absent A TRO

A TRO is necessary to prevent irreparable harm to Cardinal Health and its customers. A showing of significant loss of customers and goodwill qualifies as an irreparable injury. *BellSouth Telecomms. v. MCIMetro Access Trans. Servs.*, 425 F.3d 964, 970 (11th Cir. 2005); *Armour & Co. v. Freeman*, 304 F.2d 404, 406 (D.C. Cir. 1962) (loss of goodwill and "loss of profits which could never be recaptured" constituted irreparable harm); *Alf v. Donley*, 666 F. Supp. 2d 60, 70 (D.D.C. 2009) ("[i]njury to reputation or goodwill is not easily measurable in monetary terms, and so often is viewed as irreparable" (quoting Wright & Miller, 11A Fed. Prac. & Proc. § 2948.1)). *Patriot, Inc. v. U.S. Dep't of Housing & Urban Dev.*, 963 F. Supp. 1, 5 (D.D.C. 1997) ("[P]laintiffs have demonstrated irreparable harm in damage to their business reputation."). Costs incurred, and "time and person power spent," because of unlawful agency action also constitute irreparable losses. *Bracco Diagnostics, Inc. v. Shalala,* 963 F. Supp. 20, 28 (D.D.C. 1997).

Here, the harm suffered by Cardinal Health at the hands of DEA is certain, immediate, and irreparable. Cardinal Health will lose some customers, likely permanently, in the absence of a TRO. Giacomin Decl. ¶¶ 20-22. The Lakeland facility's inability to distribute controlled substances will cause considerable damage to Cardinal Health's reputation and ability to maintain and attract customers. *Id.* ¶ 20. Shipments of vitally important controlled substances, desperately needed by seriously ill or terminal patients, will—at a minimum—need to be rerouted from other Cardinal Health distribution facilities, resulting in pointless and, in some instances, serious delays. *Id.* ¶¶ 7-9. Moreover, Cardinal Health's customers would not want to order controlled substances from one facility and non-controlled substances from another facility. *Id.* ¶ 20. To avoid

inconvenience and splitting volume between different distributors, many of these customers will likely redirect orders to other wholesale distributors, resulting in serious and permanent loss of revenue and customers for the Lakeland facility. *Id.* ¶¶ 20-22.

The ISO would also impose significant unrecoverable costs on Cardinal Health. The effort required to reroute controlled substances from other distribution centers is massive. *Id.* ¶ 7. Just as the rerouting of trains carrying hazardous waste around the District of Columbia constituted irreparable harm in *CSX Transp., Inc. v. Williams*, 406 F.3d 667, 673 (D.C. Cir. 2005), the rerouting of distribution of controlled substances required by the ISO would "significantly decrease the capacity and flexibility" of the Cardinal Health drug distribution system, and would cause troubling delays.

The harm to Cardinal Health and its customers cannot be repaired if Cardinal Health must wait for a decision on a motion for a preliminary injunction or must wait to seek restoration of its registration through DEA's administrative process. When DEA serves an ISO, there is no statutory deadline for scheduling a hearing or determining when DEA will issue a final determination. *See* 21 U.S.C. § 824(d). Even with an ISO in effect, proceedings before DEA can take up to a year or more to be resolved. *Cf, e.g.*, Nicholas A. Sychak, d/b/a Medicap Pharmacy, DEA Docket No. 99-10, 65 Fed. Reg. 75,959 (Dec. 5, 2000) (registration was suspended on December 14, 1998, administrative hearing held on July 12 and 13, 1999, and final order issued on December 5, 2000). Cardinal Health will be irreparably harmed if the company must wait for two days, let alone two years, to resolve this matter.

III. The Balance Of Hardships Also Favors Issuance Of A TRO

The balance of hardships also supports entry of a TRO. Granting a TRO will harm

no one, including DEA. As explained above, *see supra* at 15-24, Cardinal Health's continued registration poses no imminent threat to public health. Cardinal Health no longer even distributes controlled substances to the pharmacies identified in the ISO, it has suspended controlled-substance shipments to other pharmacies it believes pose a risk of diversion, and it stands ready and willing to suspend shipments to any pharmacy DEA identifies as likely to be engaged in diversion. *See supra* at 2. In these circumstances, no harm will result from requiring DEA to follow its normal administrative procedures for revoking a distributor's registration—procedures that can be expedited (as long as DEA does not deprive Cardinal Health of its constitutional right to due process).

DEA's own conduct makes clear that the agency recognizes that a modest further delay will cause it no harm. DEA served an administrative inspection warrant against Cardinal Health on October 25, 2011. Ex. J. It then waited over three months to issue the ISO. Additionally, DEA has known how Cardinal Health's SOM Program operates since 2009, when it inspected Cardinal Health facilities pursuant to the 2008 MOA. *See* Moné Decl. ¶¶ 28-29.

On the other hand, for all of the reasons discussed above, Cardinal Health will suffer severe and irreparable harm to its business and its reputation if the ISO is left in place. The balance of hardships thus tips decidedly in favor of Cardinal Health.

IV. The Public Interest Will Be Served By Issuance Of A TRO

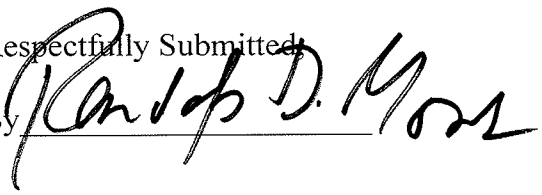
The public interest weighs heavily in favor of granting injunctive relief to Cardinal Health. As explained above, *see supra* at 15-24, Cardinal Health's continued registration poses no imminent threat to public health. The ISO would not stem the diversion of controlled substances in Florida. Just as if the state police tried to halt illegal drag racing

by shutting down a single gas station, the ISO would not achieve its claimed objective—any Lakeland facility customers who might in the future pose a risk of diversion would simply purchase their supplies from other providers. Indeed, because Cardinal Health's anti-diversion program is one of the best among wholesale drug distributors nationwide (*see* Moné Decl. ¶ 29), the shift to other distributors could actually harm the public. The delays caused by the restrictions on the Lakeland facility would also harm the public. *See supra* at 25-27. Finally, "there is an overriding public interest … in the general importance of an agency's faithful[ly] adher[ing] to its statutory mandate," *Jacksonville Port Auth. v. Adams*, 556 F.2d 52, 59 (D.C. Cir. 1977), as DEA has failed to do. For all of these reasons, the public interest weighs heavily in favor of granting a TRO.

CONCLUSION

For the reasons set forth above, Cardinal Health requests that this Court issue a TRO that prevents DEA from enforcing the ISO pending the resolution of a motion for a preliminary injunction (or other judicial proceedings).

Respectfully Submitted,

By: 

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